

# Efficacy comparison of Allevyn Gentle Border and conventional dressing in rotator cuff repair

<b>Submission date</b> 30/04/2024	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 01/05/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 17/01/2025	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Wound dressings play an essential role in the healing process by providing a physical barrier between the wound and the external environment, thereby preventing further injury or infection by opportunistic microorganisms from occurring. The optimal wound dressing should be capable of removing multifaceted obstacles in the healing process of skin wounds. Both Allevyn Gentle Border and Cosmopor E Steri1 dressings are applicable for surgical wound management. Although a single sheet of Cosmopor E Steril may seem relatively inexpensive, its limited reusability and frequent need for replacement increase the overall cost of wound management. On the other hand, while a single sheet of Allevyn Gentle Border may seem relatively expensive, its reusability for up to 7 days after removal and waterproof properties are ideal features for patient's self-management of wounds. Therefore, this study will evaluate and compare the non-inferiority of Allevyn Gentle Border compared to Cosmopor E Steri1 in wound management aiming to expand the range of dressing options for managing surgical wounds from rotator cuff repair.

### Who can participate?

Patients aged 18 to 80 years old with rotator cuff repair

### What does the study involve?

The dressings (Allevyn Gentle Border and Cosmopor E Steri1) will be placed over the surgical wound during the first dressing change post-operation. Every patient will be provided with 3 follow-up visits in the outpatient clinic 1, 2 and 4 weeks after surgery to remove the dressing and evaluate the wound condition.

### What are the possible benefits and risks of participating?

Participating patients may reduce dressing change frequency and related costs, enhance postoperative life satisfaction or may not benefit directly from this study. The study will generate essential information, which could be of benefit to others in the future.

Possible adverse events in this study may include but are not limited to peri-wound skin irritation, blistering, redness, stinging or burning while wearing the dressing, pain and itching under the dressing, dressing intolerance, skin damage from medical adhesive and allergic dermatitis. Every possible effort will be taken to minimise the potential of these risks occurring.

Where is the study run from?  
West China Hospital, Sichuan University (China)

When is the study starting and how long is it expected to run for?  
March 2024 to August 2025

Who is funding the study?  
1. National Natural Science Foundation of China  
2. Science and Technology Department of Sichuan Province

Who is the main contact?  
Prof Peng-cheng Li, hx120120@gmail.com

## Contact information

**Type(s)**  
Scientific, Principal investigator

**Contact name**  
Prof Peng-cheng Li

**Contact details**  
No.37 Guoxue Alley, Wuhou District  
Chengdu, Sichuan Province  
China  
610041  
+86 18980601911  
16699411@qq.com

**Type(s)**  
Public

**Contact name**  
Ms Jinyu Wu

**Contact details**  
No.37 Guoxue Alley, Wuhou District  
Chengdu, Sichuan Province  
China  
610041  
+86 17857314966  
624513481@qq.com

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

## Protocol serial number

National Natural Science Foundation of China grant number: 82072514, Science and Technology Department of Sichuan Province grant number: 2022JDKP0091

## Study information

### Scientific Title

Efficacy of Allevyn Gentle Border dressing versus conventional wound dressing in patients with surgical wounds from rotator cuff repair: a randomized controlled non-inferiority trial

### Study objectives

It is hypothesised that Allevyn Gentle Border dressing will be both feasible and acceptable in wound management with rotator cuff repair.

### Ethics approval required

Ethics approval required

### Ethics approval(s)

approved 17/04/2024, Ethics Committee on Biomedical Research, West China Hospital of Sichuan University (Room 412~413, Laobajiao, No.37 Guoxue Alley, Wuhou District, Chengdu, Sichuan Province, 610041, China; +86 028-65423237; huaxilunli@163.com), ref: 2024 Review (463)

### Study design

Prospective randomized parallel-controlled single-center open-label trial

### Primary study design

Interventional

### Study type(s)

Quality of life, Safety, Efficacy

### Health condition(s) or problem(s) studied

To expand the range of dressing options for managing surgical wounds from rotator cuff repair

### Interventions

This is a non-inferiority trial and cost-benefit analysis of silicone adhesive foam dressing for wound management after rotator cuff suture repair. The sample size will be 68 patients who will be randomly assigned 1:1 to an experimental group (34 patients) that will use either the study dressing (Allevyn Gentle Border) or a control dressing (34 patients) of conventional adhesive dressing (Cosmopor E Steri1). The randomization method employed is simple randomization. Specifically, participants will be randomly assigned to the experimental or control group in a 1:1 ratio according to random numbers generated by SPSS version 25.0 (SPSS Inc., Chicago, Illinois, USA). The dressings will be placed during the first dressing change post-operation. Every patient will be provided with 3 follow-up visits in the outpatient at 1 week, 2 weeks, and 4 weeks after surgery, remove the dressing and evaluate the wound condition.

### Intervention Type

Device

**Phase**

Phase 0

**Drug/device/biological/vaccine name(s)**

Allevyn Gentle Border dressing, Cosmopor E Steri1 dressing

**Primary outcome(s)**

The following primary outcome measures will be assessed using data collected from study records at 1, 2 and 4 weeks after surgery:

1. Incidence rate of wound complications
2. The cost-effectiveness of wound care, analyzed using the cost-effectiveness ratio (CER) and incremental cost-effectiveness ratio (ICER). The total direct costs related to surgical wound care will include registration fees, dressing change costs, dressing costs and the cost of management of complications

**Key secondary outcome(s)**

The following secondary outcome measures will be assessed, unless stated, using data collected from study records at 1, 2 and 4 weeks after surgery:

1. Wound healing rate
2. Healing time
3. Dressing wear time
4. Number of dressing changes
5. Clinician's evaluation of dressing performance characteristics measured using a Likert 4-point scoring method
6. Patient's evaluation of the dressing measured using a Likert 4-point scoring method

**Completion date**

31/08/2025

**Eligibility****Key inclusion criteria**

1. Age between 18 and 80 years
2. Undergoing initial rotator cuff repair
3. Surgical procedures will be performed by the same surgeon using the same surgical technique and suture materials
4. Good patient compliance and regular follow-ups are essential
5. Voluntary participation in the study with signed informed consent

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

80 years

**Sex**

All

**Key exclusion criteria**

1. Patients with conditions that may affect wound healing, including hypertension, diabetes, hypoproteinemia, malnutrition (defined as body mass index or BMI < 18.5 kg/m<sup>2</sup>), severe obesity (defined as BMI > 28 kg/m<sup>2</sup>), rheumatoid disease, tumor, connective tissue disease, hemophilia, limb vascular disease, psoriasis, radiation injury, gangrene, genetic diseases, anemia, gout, or other diseases that may affect wound healing
2. Long-term use of immunosuppressive agents, glucocorticoids, biological agents, anticoagulants, antiplatelet drugs, or no standardized adjustment and withdrawal pre-surgery
3. Long-term history of smoking or alcohol consumption
4. Preoperative history of surgery or infection at the surgical site
5. Scars, skin lesions, or rashes at the surgical site pre-surgery
6. Recent history (within 1 month) of invasive procedures, such as acupuncture, small needle knife, or drug injection at the surgical site
7. Psoriasis, eczema, dermatitis or other skin diseases
8. Allergic to any dressing components

**Date of first enrolment**

01/12/2024

**Date of final enrolment**

01/03/2025

**Locations****Countries of recruitment**

China

**Study participating centre**

**West China Hospital, Sichuan University**

No.37 Guoxue Alley, Wuhou District

Chengdu, Sichuan Province

China

610041

**Sponsor information****Organisation**

West China Hospital of Sichuan University

ROR

<https://ror.org/007mrxy13>

## Funder(s)

### Funder type

Government

### Funder Name

National Natural Science Foundation of China

### Alternative Name(s)

Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhùi, , NSFC, NNSF, NNSFC

### Funding Body Type

Government organisation

### Funding Body Subtype

National government

### Location

China

### Funder Name

Science and Technology Department of Sichuan Province

### Alternative Name(s)

Sichuan Provincial Department of Science and Technology, Department of Science and Technology of Sichuan Province, Science & Technology Department of Sichuan Province, , SPDST

### Funding Body Type

Government organisation

### Funding Body Subtype

Local government

### Location

China

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be available upon request from the corresponding author, Prof Peng-cheng Li, 16699411@qq.com.

**IPD sharing plan summary**

Available on request